

FIRST AMENDMENT AND RESPONSE TO OFFICE ACTION  
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**Remarks**

The present invention is directed to methods of increasing or diverting a pre-existing immune response in an individual by administering an immunity linker having binding sites that include polypeptides expressed by bacteriophages. After entry of the amendments, Claims 1-4, 7, 10-16 and 18 remain pending in this application. Claims 1, 10, 14, 16 and 18 have been amended. Claims 5, 6, 8, 9 and 17 have been canceled.

Support for these amendments is found at least as at page 10, lines 17-24; page 11, lines 14-20; page 5, lines 23-28; page 13, lines 15-32; page 16, lines 26-29 and page 22, lines 20-23 of the original specification.

No new matter has been added as a result of these amendments. Entry of these amendments is respectfully requested.

***Claim Rejections under 35 U.S.C. §112, second paragraph***

Claims 1-18 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant respectfully traverse the rejection as it applies to the amended claims.

Applicant further submits Claims 5, 6, 8 and 17 have been canceled herein. Accordingly, the rejection of Claims 5, 6, 8, 9 and 17 is moot.

Claims 1, 14, 16 and 18 have been amended to particularly point out and distinctly claim the subject matter which Applicant regards as the invention in compliance with 35 U.S.C. §112, second paragraph. Accordingly, Applicant respectfully requests withdrawal of this rejection.

***Claim Rejections under 35 U.S.C. §102(b)***

Claims 1-2, 4, 7, 13, 18 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,869,232 or WO 95/29938 ("Sallberg"). Applicant respectfully traverses the rejection as it applies to the amended claims

1. Applicant respectfully submits amended independent Claim 1 overcomes the rejection. The Applicant respectfully submits that Sallberg does not teach or suggest each and

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every recitation of amended independent Claim 1. Specifically, Sallberg fails to teach or suggest an immunity linker comprising a bacteriophage-expressed polypeptide binding site. Rather, Sallberg is directed to an antigen/antibody specificity exchanger "which is selected from the group consisting of a direct peptide bond and spacer molecules" such as "a covalent or a biotin-avidin-biotin link." (Col. 2, lines 31-35, and independent Claims 12 and 15, respectively).

Sallberg does not teach or suggest each and every recitation of amended independent claims 1 and 18, and therefore fails to anticipate the claimed methods. Withdrawal of this rejection is respectfully requested.

Claims 1, 2, 13 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,378,815 ("Krsmanovic"). The Applicant respectfully traverse the rejection as it applies to the amended claims.

2. Applicant respectfully submits amended independent Claim 1 overcomes the rejection. The Applicant respectfully submits that Krsmanovic does not teach or suggest each and every recitation of amended independent Claim 1. Specifically, Krsmanovic fails to teach or suggest an immunity linker comprising a bacteriophage-expressed polypeptide binding site. Rather, Krsmanovic is directed to protein:protein conjugation of an immunogenic sensitizing agent (e.g., any immunogenic molecule with the necessary properties set forth in Krsmanovic Col. 3, lines 3-27) to a targeting agent (e.g., chicken autocrine differentiation-inhibiting factor). (Col. 2, lines 60-68; Col. 3, lines 1-30; Col. 4, lines 26-27; Col. 7, lines 14-15; and Figure 1).

Krsmanovic does not teach or suggest each and every recitation of amended independent Claim 1, and therefore fails to anticipate the claimed invention. Withdrawal of this rejection is respectfully requested.

*Claim Rejections under 35 U.S.C. §102(a) or (e)*

Claims 1-3, 5, 13 and 18 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Marinkovich (US 2003/0108555). The Applicant respectfully traverse the rejection as it applies to the amended claims.

1. Applicant respectfully submits amended independent Claim 1 overcomes the rejection. The Applicant respectfully submits that Marinkovich does not teach or suggest each

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and every recitation of amended independent Claim 1. Specifically, Marinkovich fails to teach or suggest an immunity linker comprising a bacteriophage-expressed polypeptide binding site. Rather, Marinkovich is directed to "the [EDC] conjugation of antigens, including viruses, to monoclonal antibodies and the [EDC] conjugation of antigens to viruses." (Page 4, para. [0061], and page 4, para. [0062]-[0064], and independent Claim 1).

Applicant further submits Claim 5 has been canceled herein. Accordingly, the rejection of Claim 5 is moot.

Marinkovich fails to teach or suggest each and every recitation of amended independent Claim 1, and therefore fails to anticipate the claimed methods. Withdrawal of this rejection is respectfully requested.

*Claim Rejections under 35 U.S.C. §102(b) or (e)*

Claims 1-7 and 12-18 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Pouletty (WO 97/37690 or US 2006/0002891). The Applicant respectfully traverse the rejection as it applies to the amended claims.

1. Applicant respectfully submits amended independent Claim 1 overcomes the rejection. The Applicant respectfully submits that Pouletty does not teach or suggest each and every recitation of amended independent Claim 1. Specifically, Pouletty fails to teach or suggest an immunity linker comprising a bacteriophage-expressed polypeptide binding site. Rather, Pouletty is directed to "complexines," conjugates comprising an endogenous effector agent (such as, according to the Examiner on page 6 of the present Non-Final Office Action, "an antigen to which ... the host has previously formed antibodies or T-cells") and a target epitope (such as, according to the Examiner on page 6 of the present Non-Final Office Action, "a ligand for a cell surface receptor or an antibody of Fab fragment ... directed to a cell surface receptor") for modulation of a target cell. (Page 2, para. [0018]-[0019]).

Pouletty does not teach or suggest each and every recitation of amended independent Claim 1, and therefore fails to anticipate the claimed methods. Withdrawal of this rejection is respectfully requested.

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Claims 1-2, 4-7, 12-13 and 18 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Low et al (US 2001/0031252 or US 7,033,594). The Applicant respectfully traverse the rejection as it applies to the amended claims.

2. Applicant respectfully submits amended independent Claim 1 overcomes the rejection. The Applicant respectfully submits that Low does not teach or suggest each and every recitation of amended independent Claim 1. Specifically, Low fails to teach or suggest an immunity linker comprising a bacteriophage-expressed polypeptide binding site. Therefore, Low does not teach or suggest each and every recitation of amended independent Claim 1, and therefore fails to anticipate the claimed methods.

Claims 1, 2, 5-6, 13, 14 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cowan (WO 01/32207). The Applicant respectfully traverse the rejection as it applies to the amended claims.

3. Applicant respectfully submits amended independent Claim 1 overcomes the rejection. The Applicant respectfully submits that Cowan does not teach or suggest each and every recitation of amended independent Claim 1. Specifically, Cowan fails to teach or suggest an immunity linker comprising a bacteriophage-expressed polypeptide binding site. Rather, Cowan is directed to a hapten-ligand conjugate that "functions to provide binding sites of the appropriate types so that presensitized immune cells can bind with the target antigen complex." (page 6, para. 2, and independent Claims 1 and 7).

Applicant further submits Claims 5 and 6 have been canceled herein. Accordingly, the rejection of Claims 5 and 6 is moot.

Cowan does not teach or suggest each and every recitation of amended independent Claim 1, and therefore fails to anticipate the claimed methods. Withdrawal of this rejection is respectfully requested.

***Claim Rejections under 35 U.S.C. §103(a)***

Claims 1 and 16-17 have been rejected under 35 U.S.C. §103(a) for being unpatentable over Marinkovich, Pouletty, Low et al or Cowan, any or all in view of Rhodes (4,940,670). The Applicant respectfully traverse the rejection as it applies to the amended claims

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Markinvoch, Pouletty, Low, or Cowan have been discussed above as they apply to the amended claims. The Applicant respectfully submits that these references in combination fails to render obvious the claimed invention because they do not teach or suggest each and every recitation of amended independent Claim 1. Rhodes fails to make up for these deficiencies, therefore, the prior art alone, or in combination, fails to teach or suggest the claimed invention directed to an immunity linker comprising a bacteriophage-expressed polypeptide binding site and a binding site for a universal immunogen.

Furthermore, the combined references fail to provide any suggestion or motivation to utilize an immunity linker comprising a bacteriophage-expressed polypeptide binding site as claimed.

Applicant further submits Claim 17 has been canceled herein. Accordingly, the rejection of Claim 17 is moot.

Applicant respectfully submits the claimed invention as amended is non-obvious over the prior art and respectfully requests withdrawal of this rejection.

#### *Double Patenting*

Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 10-13 of copending Application No. 10/178,046.

Applicant respectfully submits that '046 became abandoned on December 1, 2006 and, therefore, is no longer co-pending with the present application. Therefore, the provisional rejection of Claims 1-18 on the ground of non-statutory obviousness-type double patenting as being unpatentable over Claims 8 and 10-13 of '046 is moot.

Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/754,756.

Applicant respectfully submits that the present amendment to independent Claim 1 overcomes this rejection and the '756 claimed subject matter does not encompass that of amended independent Claim 1. Withdrawal of this rejection is respectfully requested.

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**CONCLUSION**

Applicant submits the foregoing as a full and complete response to the Non-Final Office Action mailed on September 12, 2006. The Applicant and the undersigned respectfully submits that the present application is in condition for allowance. Such action is hereby courteously solicited.

If the Examiner believes there are other issues that may be resolved by telephone interview, or that there are any informalities remaining in the application that may be corrected by Examiner's Amendment, a telephone call to the undersigned is respectfully requested.

Other than the fee to accompany the petition for a three-month extension of time, no additional fees are believed to be due in connection with this response. However, should the Commissioner determine otherwise, the Applicant hereby authorizes the Commissioner to charge such fees and credit any overpayment to Deposit Account No. 11-0980.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



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